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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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PACESETTER, INC.
15900 Valley View Court
Sylmar, CA 91392-9221

EXAMINER

OROPEZA, FRANCES P

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| ART UNIT | PAPER NUMBER |
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3762

DATE MAILED: 12/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/961,121

Applicant(s)

LEVINE, PAUL A.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2001 (Initial Filing).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 is unclear because in line 2 it appears "an average sinus interval" should be --the average sinus interval--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 5-15, 25-30, 32, 33, 35-37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by McClure et al. (US 5560369).

Mc Clure et al. teach a cardiac arrhythmia detection system for an implantable device that senses atrial and ventricular sinus events /rhythmic event and ectopic events/ arrhythmic events/ PVCs (abstract; figure 8; col. 1 @ 10-16 and 48-59; col. 6 @ 50-58; col. 12 @ 22-31; col. 19 @ 47-67). Sensing thresholds for the pre-amplifier (42) are automatically set (col. 5 @ 41-64; col. 14 @ 44-48; col. 22 @ 59-62) and calibration periodically repeated

(col. 2 @ 17-35; col. 10 @ 14-20). The sensing thresholds and timing relationships of the intervals are stored (col. 7 @ 8-14; col. 8 @ 29-32; col. 12 @ 32-67; col. 13 @ 36-45; col. 14 @ 3-17). Cardiac events are classified based on the proximity to thresholds (col. 10 @ 66 – col. 11 @ 16). Cardiac events are classified based on proximity to the previous average cycle length (col. 10 @ 40-65).

As to claims 2, 3, 7-10, 29, 30, 36 and 37, rhythmic consistency and lack of rhythmic consistency are determined (col. 10 @ 66 – col. 11 @ 16; col. 16 @ 5-7) by sampling two consecutive intervals (col. 16 @ 56-65).

As to claims 11-12, seventy five percent, read as seventy percent, of the baseline value is used to denote significant change (col. 6 @ 16-25) and sensitivity is adjusted based on ectopic event history (col. 8 @ 62 - col. 9 @ 37).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint Inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. The Applicant is advised of the obligation under 37 CFR 1.56 to point

out the Inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over McClure et al. (US 5560369) in view of Weinberg et al. (US 5476485). As discussed in paragraph 4 of this action, McClure et al. disclose the claimed invention except for maintaining a sensitivity setting of a first amplifier while adjusting a sensitivity setting of a second sense amplifier.

Weinberg et al. teach amplifier sensitivity adjustment using two amplifiers and maintaining a sensitivity setting of a first amplifier (32) while adjusting a sensitivity setting of a second sense amplifier (64) for the purpose discriminating between signals. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used two amplifiers and maintaining a sensitivity setting of a first amplifier while adjusting a sensitivity setting of a second sense amplifier in the McClure et al. system in order to automatically provide signal clarity enabling optimum functioning of the implanted device (col. 1 @ 7-13; col. 1 @ 61 – col. 2 @ 12; col. 6 @ 43-67).

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over McClure et al. (US 5560369) in view of Mann et al. (US 5476485). As discussed in paragraph 4 of this action, McClure et al. disclose the claimed invention except for the data retrieved from the implanted device being displayed as a histogram.

Mann et al. teach data display using a histogram for the purpose of visually presenting cardiac data to the physician. It would have been obvious to one having ordinary skill in the art

at the time of the invention to have used a histogram in the McClure et al. system in order to enable the physician to easily evaluate the cardiac activity and the effectiveness of treatment (abstract; col. 6 @ 27 – col. 7 @ 11; col. 25 @ 10-14).

7. Claim 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over McClure et al. (US 5560369) in view of Schuelke et al. (US 6112119). As discussed in paragraph 4 of this action, McClure et al. discloses the claimed invention except for detecting a PVC based on the presence or absence of an atrial event (claims 17-18) where the average A-V interval is used to determine the sinus or ectopic nature of the event (claims 19-21), and determining and storing the A-V interval using a window (claims 22-24).

Schuelke et al. teach cardiac signal sensing using adjustment of the amplifier sensitivity/gain with the following methods: detecting a PVC based on the presence or absence of an atrial event where the average A-V interval is used to determine the sinus or ectopic nature of the event, and determining and storing the A-V interval using a window for the purpose of accurately interpreting the nature of the cardiac signals. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the following methods: detecting a PVC based on the presence or absence of an atrial event where the average A-V interval is used to determine the sinus or ectopic nature of the event, and determining and storing the A-V interval using a window in the McClure et al. system in order to avoid improper device settings for the particular patient and situation so the implantable cardiac device operates effectively (abstract; col. 3 @ 53-63; col. 4 @ 26-53; col. 8 @ 8-13; col. 9 @ 22-34; col. 11 @ 22-25; col. 19 @ 3-13; col. 26 @ 35-57; col. 27 @ 1-15; col. 31 @ 58-65; col. 34 @ 25-45; col. 44 @ 33-39).

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist at telephone number (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
11/30/03

Angela D. Sykes

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